United States District Court
District of Massachusetts

Angela Barnes,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 22-10496-NMG**
	)	
Merck & Co., Inc., Merck Sharp & Dohme Corp., Organon & Co. and Organon, LLC,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM & ORDER

Plaintiff Angela Barnes ("Barnes" or "plaintiff") brings this personal injury action against Merck & Co, Inc. and Merck Sharp & Dohme Corp. ("Merck defendants" or "Merck") and Organon & Co. and Organon, LLC ("Organon defendants" or "Organon") (all collectively referred to as "defendants").

The case arises from allegations that plaintiff's neuropsychiatric injuries were caused by Singulair, a pharmaceutical product manufactured by Merck. Plaintiff, who was prescribed Singulair, asserts that Merck knew or should have known of the risks of those injuries prior to selling the product. She brings claims for design defect, failure to warn, negligence, misrepresentation and breach of express warranty. Pending before the Court is defendants' motion to dismiss.

I. Background

A. Singulair

Singulair, which contains the active ingredient montelukast, was patented by Merck in 1996 and received approval for use from the Food and Drug Administration ("FDA") in 1998. Merck was the exclusive manufacturer, distributor and seller of Singulair from 1998 to mid-2012, when its patent expired. At that point, other companies were approved to market generic montelukast in the United States. Singulair is indicated for (1) prophylactic and chronic treatment of asthma, (2) acute prevention of exercise-induced bronchoconstriction ("EIB") and (3) relief of symptoms of allergic rhinitis.

The complaint alleges that montelukast has been tested extensively and many of those studies demonstrate a correlation between Singulair usage and the development of neuropsychiatric events. As set forth in the complaint, montelukast crosses the blood-brain-barrier, which is a semi-permeable membrane of cells that protects the brain and the central nervous system from pathogens. Very few drugs are able to pass the blood-brain-barrier to impact the central nervous system. Because montelukast does so, it purportedly exerts a systemic effect upon the central nervous system that results in, among other things, adverse neuropsychiatric events.

When Singulair was first introduced to the market in 1998, the label contained no warnings regarding neuropsychiatric events. According to the complaint, Merck has since "belatedly added grossly insufficient warnings" to the product label. In March, 2020, the FDA required Merck to add a "Black Box Warning," the strongest kind of warning, to the Singulair label to warn that "serious neuropsychiatric events have been reported in patients taking Singulair."

B. The Parties

The Merck defendants are New Jersey corporations that manufacture and sell pharmaceutical drugs. Their subsidiaries, the Organon defendants, are headquartered in Delaware. According to the complaint, Merck has maintained control of the brand name "Singulair" until at least 2020 and perhaps even through the filing date of the complaint. Plaintiff alleges that she believes Merck "spun off" Singulair to its subsidiary Organon after the FDA ordered Merck to add the Black Box Warning to the label.

The complaint asserts that Merck manufactured, marketed and sold millions of Singulair pills in Massachusetts, including those that plaintiff allegedly ingested. Moreover, the defendants allegedly engaged in an extensive campaign to educate Massachusetts physicians about the purported benefits of

Singulair and misrepresented the safety of the drug. The defendants also apparently engaged in direct-to-consumer advertising in Massachusetts, including in print magazines and television commercials.

Plaintiff Barnes resides in Norfolk County, Massachusetts and was prescribed Singulair from 2014 to 2018. As alleged in the complaint, her prescriptions were filled with "branded and/or generic Singulair." Plaintiff contends she used Singulair as prescribed and, as a direct and proximate result of ingesting Singulair, suffered neuropsychiatric injuries including depression, anxiety and obsessive-compulsive disorder ("OCD").

C. Procedural History

Plaintiff initiated this suit in the Massachusetts Superior Court for Norfolk County in March, 2022. Defendants removed the case to this Court based upon diversity jurisdiction and timely moved to dismiss plaintiff's claims.

Defendants also filed a District of Massachusetts Local Rule 40.1(g)(5)(B)(1) certification designating the present case as related to seven other pending cases in this district. Defendants asserted that all plaintiffs in those cases sought damages for neuropsychiatric injuries allegedly caused by branded or generic Singulair and, other than the identities of

the plaintiffs, the dates of usage and specific kinds of neuropsychiatric injures, the allegations in the complaints were essentially the same. Defendants contended that they will assert common legal defenses in all of the cases.

The judge assigned to the case, United States District Judge Richard G. Stearns, ruled, however, that the factual disparities among the individual plaintiffs' cases——including: (1) broad differences in the time periods and frequencies during which plaintiffs were prescribed Singulair or its generic (between 2000 and 2020), (2) the intervening changes in the contents of the published warnings during that same time span, and (3) the predictable differences with respect to individual damages and causation——fail the "related civil case" standard set forth in the District of Massachusetts Local Rule 40.1. Judge Stearns concluded there were no circumstances under which a joint trial of the cases would be practicable.

Accordingly, Judge Stearns returned all but the first-filed case to the Court Clerk for reassignment. The case at bar, as well as Ortega v. Merck & Co., Inc., 22-10511, were assigned to this session.

II. Motion to Dismiss Due to Lack of Jurisdiction

Defendants move to dismiss the complaint for lack of personal jurisdiction pursuant to Fed. R. Civ. P. 12(b)(2).

Barnes bears the burden of showing that the Court has authority to exercise jurisdiction over defendants. Cossart v. United Excel Corp., 804 F.3d 13, 18 (1st Cir. 2015). Where, as here, the Court decides a motion to dismiss for lack of personal jurisdiction without first holding an evidentiary hearing, the Court takes plaintiff's

> properly documented evidentiary proffers as true and construe[s] them in the light most favorable to [plaintiff's] jurisdictional claim.

A Corp. v. All Am. Plumbing, Inc., 812 F.3d 54, 58 (1st Cir. 2016). A plaintiff cannot, however, rely on

> unsupported allegations [and] must put forward evidence of specific facts to demonstrate that jurisdiction exists.

Id. (quotations and citations omitted).

In a diversity suit such as this one, this Court acts as "the functional equivalent of a state court sitting in the forum state." Astro-Med, Inc. v. Nihon Kohden America, Inc., 591 F.3d 1, 8 (1st Cir. 2009). As such, plaintiff must demonstrate that the exercise of personal jurisdiction is permitted by the Massachusetts long-arm statute, M.G.L. c. 223A § 3, and coheres with the Due Process Clause of the Fourteenth Amendment by showing that defendant has "minimum contacts" with the Commonwealth. Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A., 290 F.3d 42, 52 (1st Cir. 2002).

This Court's jurisdiction may be either "specific" or "general." United States v. Swiss Am. Bank, 274 F.3d 610, 618 (1st Cir. 2001). Specific jurisdiction requires a "demonstrable nexus" between the claims of the plaintiff and the defendant's contacts in the forum state. Id. Those contacts must demonstrate that defendant "purposeful[ly] avail[ed] [itself] of the privilege of conducting activities in the forum state." Noonan v. Winston Co., 135 F.3d 85, 90 (1st Cir. 1998). General jurisdiction, on the other hand, exists when the defendant has "engaged in continuous and systematic activity, unrelated to the suit, in the forum state." Swiss Am. Bank, 274 F.3d at 618.

A. Massachusetts Long-Arm Statute

The Massachusetts long-arm statute provides, in relevant part, that a court may exercise personal jurisdiction:

> over a person, who acts directly or by an agent, as to a cause of action in law or equity arising from the person's . . . (d) causing tortious injury in this commonwealth by an act or omission outside this commonwealth if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in this commonwealth . . . .

M.G.L. c. 223A, § 3(d). The requirements of the Massachusetts long-arm statute are substantially similar to (although potentially more restrictive than) those imposed by the federal Due Process Clause. See Copia Commc'ns, LLC v. AMResorts, L.P.,

812 F.3d 1, 4 (1st Cir. 2016); Baskin-Robbins Franchising LLC v. Alpenrose Dairy, Inc., 825 F.3d 28, 34 (1st Cir. 2016). This Court independently analyzes personal jurisdiction pursuant to that statute due to the distinction between the two regimes.

Defendants argue that § 3(d) is the Massachusetts equivalent of general jurisdiction, citing Hopkins v. Yi, and thus contend that it is inapplicable to the specific jurisdiction inquiry here. No. 18-40197, 2019 WL 3547085, at *4 (D. Mass. May 31, 2019). Courts in this district have, however, held that § 3(d) can be applied to general or specific jurisdiction. See Ching-Yi Lin v. TipRanks, Ltd., No. 19-11517, 2019 WL 6211246, at *7 n.3 (D. Mass. 2019) (noting that the long-arm statute "would likely also be satisfied under section 3(d)"); Merced v. JLG Indus., Inc., 170 F. Supp. 2d 65, 72 (D. Mass. 2001) (finding specific jurisdiction under § 3(d)); Digital Equip. Corp. v. AltaVista Tech., Inc., 960 F. Supp. 456, 467 n.23 (D. Mass. 1997) (concluding that "Section 3(d) embraces specific jurisdiction as well [as general jurisdiction], and does so in this case").

It is the duty of the Court to "interpret the statute to effectuate a State's legitimate desire to protect its citizens" as long as the bounds of constitutional due process are not crossed. Mark v. Obear & Sons, Inc., 313 F. Supp. 373, 376 (D.

Mass. 1970). Given that duty and the precedent concluding that § 3(d) embraces the theory of specific jurisdiction, this Court concludes, as it has previously, that § 3(d) can be used to establish specific jurisdiction over a defendant. See Merced, 170 F. Supp. 2d at 72.

The threshold requirement of § 3(d) is that the defendants' out-of-state act caused the plaintiff's in-state harm. Id. at 71. Actions taken by defendants outside the Commonwealth, in this case, in New Jersey and Pennsylvania, to manufacture and create the Singulair label are the proximate cause of plaintiff's alleged neuropsychiatric injuries suffered in Massachusetts. That is the case even if plaintiff took only the generic montelukast because the FDA requires that the generic drug label must be "identical to the warning label of its brand-name counterpart." Rafferty v. Merck & Co., 92 N.E.3d 1205, 1214-15 (Mass. 2018). Moreover, the brand-name drug manufacturer bears responsibility for the accuracy and adequacy of its label "as long as the drug is on the market." Wyeth v. Levine, 555 U.S. 555, 570-71 (2009).

Next, plaintiff must satisfy one of the three disjunctive prongs of the second requirement of § 3(d): (1) engaging or soliciting business in Massachusetts, (2) engaging in any other persistent course of conduct in Massachusetts, or (3) deriving

substantial revenue from goods used or consumed in Massachusetts. M.G.L. c. 223A, § 3(d).

Barnes argues that defendants are clearly subject to jurisdiction in Massachusetts because they manufactured, marketed and sold millions of Singulair pills in Massachusetts and engaged in extensive advertising campaigns directed toward both the public and physicians. Most notably, plaintiff contends that she has presented adequate evidence to satisfy the substantial revenue requirement of § 3(d) by pleading that defendants sold millions of Singulair pills in Massachusetts. Although she does not describe a specific amount of revenue derived from Massachusetts, that is not a requirement. The First Circuit has held that "[i]t is well settled under Massachusetts law that 'substantial revenue' is not an absolute amount nor an absolute percentage of total sale." Keds Corp. v. Renee Int'l Trading Corp., 888 F.2d 215, 219 (1st Cir. 1989). Plaintiff makes a prima facie showing that defendants generate substantial revenue in Massachusetts from the sale of Singulair. See id. ("The sale of 6000 pairs of shoes for $15,000 easily meets this requirement.").

B. Due Process Clause

Plaintiff must also demonstrate that the Court's exercise of personal jurisdiction over defendants comports with the

United States Constitution. See Int'l Shoe Co. v. State of Wash., Office of Unemployment Comp. & Placement, 326 U.S. 310, 316 (1945). Barnes does not contend that this Court has general jurisdiction over defendants, thus it is only necessary to determine whether specific personal jurisdiction pertains. To support the Court's exercise of such jurisdiction, plaintiff must make an "affirmative showing" that: (1) the litigation relates to or arises out of the defendant's contacts with the forum state, (2) defendant purposefully availed itself of the privilege of conducting business in the forum state and (3) jurisdiction over the defendant is reasonable under the circumstances. Sawtelle v. Farrell, 70 F.3d 1381, 1388-89 (1st Cir. 1995); Phillips Exeter Academy v. Howard Phillips Fund, Inc., 196 F.3d 284, 288 (1st Cir. 1999).

1. Relatedness

The relatedness inquiry asks whether the plaintiff's claims "directly arise[] out of, or relate[] to" the defendants' activities in the forum state. Astro-Med, Inc., 591 F.3d at 9. The standard "is functionally the same as the statutory requirement" of the Massachusetts long-arm statute. M-R Logistics, LLC v. Riverside Rail, LLC, 537 F. Supp. 2d 269, 277 (D. Mass. 2008). Moreover, although the phrase "relate to" incorporates real limits, the United States Supreme Court

reiterated in its most recent personal jurisdiction decision that it has "never framed the specific jurisdiction inquiry as always requiring proof of causation." Ford Motor Co. v. Montana Eighth Jud. Dist. Ct., 141 S. Ct. 1017, 1026, 1028-30 (2021) (holding that Ford's marketing, advertising, service and sales activities in the forum states were related to plaintiffs' products liability claims).

As described supra, defendants' extensive Singulair marketing and advertising campaigns in Massachusetts, as well as its actions manufacturing, marketing and selling millions of Singulair pills over a 14-year period in the Commonwealth, satisfy that requirement. The Singulair packaging contained the warning label that forms the basis of plaintiff's claims. See Whaley v. Merck & Co., No. 21-cv-01985, 2022 WL 1153151, at *6 (S.D. Cal. Apr. 12, 2022) ("[I]t is conceivable that [plaintiff's] physician prescribed generic montelukast because the physician had been influenced by Singulair's advertising campaign or Singulair's presence on the formularies of [state] health insurers or past patient request[s] for Singulair that resulted from Defendants' direct-to-consumer advertising."). As a result, the Court concludes that under Ford, the claims here sufficiently relate to defendants' Singulair activities in Massachusetts. See 141 S. Ct. at 1028-30.

2. Purposeful Availment

To satisfy the second requirement, a plaintiff must demonstrate that defendant's in-state contacts represent a "purposeful availment" of the privilege of conducting business in the forum state such that it may be said the defendant invoked the benefits and protections of the laws of the forum state and its involuntary presence in a court in the forum state was foreseeable. Astro-Med, Inc., 591 F.3d at 10.

> Th[e] purposeful available requirement ensures that a defendant will not be haled into a jurisdiction solely as a result of random, fortuitous, or attenuated contacts, or . . . unilateral activity of another party or a third person.

Burger King Corp. v. Rudzewicz, 471 U.S. 462, 475 (1985) (citations and quotations omitted). The focus is on "voluntariness and foreseeability." N. Laminate Sales, Inc. v. Davis, 403 F.3d 14, 25 (1st Cir. 2005).

Here, defendants voluntarily maintain a research campus in Boston, Massachusetts, conduct systematic public advertising and physician education campaigns and sell millions of Singulair pills in the Commonwealth. Those contacts indicate that defendants intentionally availed themselves of the privilege of conducting business in the forum state.

Moreover, defendants should have reasonably foreseen that they would be brought into court in Massachusetts.

Massachusetts law places liability on the defendants for Singulair's label even if plaintiff did not ingest that drug. Rafferty, 92 N.E.3d at 1214-15. Defendants knew or should have known that a generic montelukast drug would be introduced when their patent expired in 2012 and that, pursuant to the Hatch-Waxman Amendments of 1984, its warning label would be identical to the Singulair label. Furthermore, given defendants' close, voluntary contacts with Massachusetts in operating their business, they were undoubtedly aware of the regulatory landscape and had the reasonable expectation of being haled into court here. World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980).

3. Reasonableness

Finally, the plaintiff must demonstrate that the Court's exercise of jurisdiction is reasonable. The Supreme Court has provided a set of "gestalt factors" to consider in evaluating reasonableness which include: (1) the defendant's burden of appearing, (2) the forum state's interest in adjudication, (3) the plaintiff's interest in convenient and effective relief, (4) the judicial system's interest in obtaining the most efficient resolution and (5) the shared societal interest in promoting fundamental substantive social policies. Burger King, 471 U.S. at 477 (1985).

Considering those factors, the Court's exercise of jurisdiction over defendants is fair and reasonable. With respect to the first factor, courts recognize that it is often burdensome to appear in a foreign jurisdiction. See, e.g., Sigros v. Walt Disney World Co., 129 F. Supp. 2d 56, 68-69 (D. Mass. 2001). For the first factor to have any significance, however, a defendant must demonstrate that the exercise of jurisdiction is "onerous in a special, unusual, or other constitutionally significant way." Pritzker v. Yari, 42 F.3d 53, 64 (1st Cir. 1994). Defendants proffer no reason why their burden of litigating in Massachusetts would be unusually onerous. They are multinational pharmaceutical companies which already operate facilities and conduct business in Massachusetts. Comparatively, it would be a far greater burden on plaintiff to have to litigate her claim outside of her home state. This factor therefore weighs heavily in favor of exercising jurisdiction.

As to the second factor, Massachusetts "has a significant interest in redressing injuries that actually occur within the state." Keeton v. Hustler Magazine, Inc., 465 U.S. 770, 776 (1984). In the instant case, plaintiff was prescribed, purchased and ingested the drugs in Massachusetts and suffered the alleged injury here. The interest of the Commonwealth in

adjudicating this dispute and protecting its residents from pharmaceutical-related injuries is strong and clear.

The third factor also weighs in favor of exercising jurisdiction because Barnes's chosen venue is Massachusetts. See Sawtelle, 70 F.3d at 1395. Plaintiff's most convenient forum to litigate her claim is "unquestionably" in her home state rather than elsewhere. Id.

The fourth factor is the interstate judicial system's interest in achieving the most efficient resolution of the action. This case is brought by one plaintiff, a resident of Massachusetts and thus "the interest of the judicial system in the effective administration of justice does not appear to cut in either direction" in this case. Ticketmaster-New York, Inc. v. Alioto, 26 F.3d 201, 211 (1st Cir. 1994).

Finally, the fifth factor weighs in favor of exercising jurisdiction because the most salient societal interest is the ability of Massachusetts to provide a convenient forum for its residents to redress injuries inflicted by out-of-state actors, in this case, multinational pharmaceutical corporations. See Sawtelle, 70 F.3d at 1395.

The several factors considered together demonstrate that this Court's exercise of personal jurisdiction over defendants satisfies constitutional requirements.

III. Motion to Dismiss Design Defect Claims

Notwithstanding the jurisdictional analysis, defendants move for this Court to dismiss plaintiff's design defect claims for three reasons: they are (1) barred under comment k of the Restatement (Second) of Torts § 402A, (2) preempted by federal precedent and (3) defendants did not manufacture or sell the product that allegedly injured plaintiff.

Regardless of whether Barnes ingested Singulair or the generic drug, her design defect claims are preempted by federal law. See 21 C.F.R. § 314.70(b)(2) (listing major changes that require FDA approval prior to distribution of the altered product). A pharmaceutical company cannot unilaterally implement "major changes" to the chemical formulation of a medication that the FDA has previously approved. Gustavsen v. Alcon Labs., Inc., 903 F.3d 1, 10 (1st Cir. 2018) ("Major changes require approval from the FDA prior to implementation, while moderate and minor changes do not.").

In her complaint, Barnes suggests that safer, feasible alternative designs for Singulair were available, including modifying montelukast itself and modifying Singulair without modifying montelukast, both with the goal of making it less likely that montelukast would cross the blood-brain-barrier and contribute to adverse neuropsychiatric events. Because those

are "major changes" to the formation of Singulair pursuant to 21 C.F.R. § 314.70(b)(2), federal law preempts such a cause of action because the defendants cannot lawfully make such a change without prior FDA approval. See id.

Thus, the Court will dismiss Count I (design defect) and Count III (negligence) insofar as Count III alleges negligent design.

Plaintiff has requested in her opposition brief leave to amend her complaint if the Court allows defendants' motion to dismiss as to any of her claims. In this current posture, plaintiff's request will be denied. Although Fed. R. Civ. P. 15(a)(2) encourages the free allowance of leave to amend "when justice so requires," no prospective change to Barnes's complaint could alter the fact that any claim against defendants with respect to Singulair's design is preempted by federal law.

ORDER

For the foregoing reasons, defendants' motion to dismiss (Docket No. 12) is,

1) with respect to Count I (design defect) and Count III (negligence), insofar as Count III alleges negligent design, **ALLOWED**, but

2) with respect to personal jurisdiction, **DENIED**, and

3) with respect to plaintiff's request to amend her complaint, **DENIED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated January 4, 2023